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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/006,881	12/10/2001	Manfred Reiter	V-260.00	2884
7590 06/15/2004				
Baxter Healthcare Corporation				
P. O. Box 15210				
Irvine, CA 92614				
EXAMINER				
CHEN, STACY BROWN				
ART UNIT				
PAPER NUMBER				
1648				

DATE MAILED: 06/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

### Application No.

10/006,881

### Applicant(s)

REITER ET AL.

### Examiner

Stacy B Chen

### Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on March 25, 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-9, 11-19, 21 and 24-38 is/are pending in the application.
- 4a) Of the above claim(s) 24-38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9, 11-19 and 21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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### **DETAILED ACTION**

1. Applicant's response filed March 25, 2004 is acknowledged and entered. Claims 1-9, 11-19, 21 and 24-38 are pending. Claims 1-9, 11-19 and 21 are under examination.
2. The rejection of claim 6 under 35 U.S.C. 112, second paragraph, is withdrawn in view of Applicant's amendment.

### ***Response to Arguments***

3. The rejection of claims 1, 2, 4, 5 and 11-12 under 35 U.S.C. 102(b) as anticipated by Caij *et al.*, "Caij", is maintained for reasons of record. The rejection of claims 3, 6, 7-9, 13-19 and 21 under 35 U.S.C. 103(a) as obvious over Caij and further in view of Kessler *et al.*, "Kessler", and Merten *et al.*, "Merten", is maintained for reasons of record. Applicant's arguments have been carefully considered, but fail to persuade.

Applicant's substantive argument is primarily directed to the assertion that Caij fails to teach a method wherein the cell density is increased in the microcarriers. In response, the claims do not recite that the cell density is increased in the microcarriers. Even if the claims had been amended to recite the supposed limitation, the specification does not appear to support "increased in the microcarriers". Applicant argues that Caij increases cell density by moving the cells to microcarriers. In response, the claims do not specify the method by which cell density is increased. Further, cell density was increased by reducing the volume of growth medium.

Applicant also argues that the invention provides the unexpected results of prolonged cell culture time, continuously produced viral antigen and overall viral production efficiency. In response, since the claimed method steps are the same as Caij's steps, one would expect the same

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results as Applicant. The steps in Caij's method are: 1) culture cells in flasks and prepare microcarriers, 2) transfer cells from flasks to microcarriers, 3) allow microcarriers to be 100% covered with cells, 4) subpassage cultures, 5) remove growth medium from microcarrier culture and add virus suspension, 6) allow virus to infect cells for one hour, and 7) add medium back in and harvest the supernatant 48 hours later. Caij's virus suspension is added to the microcarrier culture, without the growth medium, and then allowed to incubate for one hour. The cell density is increased when the microcarriers, cells, and virus are present. Therefore, these method steps (Caij, pages 113-115) read on Applicant's method steps and are anticipated or obvious over Caij.

### ***Conclusion***

4/3. No claim is allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stacy B. Chen whose telephone number is 571-272-0896. The examiner can normally be reached on M-F (7:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James C. Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Stacy B. Chen  
June 9, 2004

  
6/13/04

JAMES HOUSEL  
SUPERVISORY PATENT EXAMINER  
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